REMARKS

Claims 1, 2, 5-8, 9-13, 15, 18-35, and 37-49 were pending. Claims 1, 2, 5, 6, 7, 8, 9, 18, 20, 27, 28, 33, 42, 43, 45, and 47 have been amended. Claim 50 has been added. Upon entry of this amendment, claims 1, 2, 5-8, 9-13, 15, 18-35, and 37-50, will be pending. Claims 1, 2, and 5-8, and 50 are under examination.

Although, the claims complied with all requirements for patentability the claims have been amended as suggested by the Examiner to change the term "lipoparticle" to "virus-like particle." Support for such amendment can be found throughout the specification including, for example, paragraphs 0084 and 0203 of the published application .

The claims have also been amended to recite that the multiple membrane spanning protein is a "protein of interest." Support for this amendment can be found throughout the specification, including, for example, page 18, first full paragraph, of the as-filed specification. The invention is directed to incorporating a select multiple membrane spanning protein into the virus-like particle.

New claim 50 has been added which recites that the protein of interest is a heterologous protein, support for which can be found throughout the specification, and, for example, in the Examples section of the present application.

No new matter has been added.

Preliminarily, Applicants thank Examiner Parkin for the helpful interview. The suggestions made by Examiner Parkin during the interview have been incorporated throughout this response.

Rejection under 35 U.S.C. § 112

Claims 1,2 and 5-8 were rejected under 35 U.S.C. § 112, first paragraph as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Office alleges that the claims are

> broadly directed toward a lipoparticle of undefined structure comprising a multiple membrane spanning protein of undefined structure. Concerning the membrane spanning protein, the only

> limitation provided is a negative one that simply specifies that the protein cannot be CD63. However, it fails to provide any further illumination on the structure of the protein. Concerning the lipoparticle, the claims fail to provide any structural limitations. Perusal of the disclosure fails to review any significant teachings that would lead the skilled artisan to any particular structure. Thus the skilled artisan would reasonably conclude that applicants were not in possession of the claimed invention at the time of filing.

(Office Action, pages 3-4). Applicants traverse this rejection.

As discussed during the interview, the case law cited by the Office in support of this rejection is not relevant to the pending claims in the present application. The cases cited by the Office are directed, *inter alia*, to written description defects in claims directed to nucleic acid sequences of genes that have not been cloned and to chemical sub-genuses that were not described. Neither of these fact patterns apply to the present invention. The present invention is not directed to nucleic acid sequences or chemical sub-genuses.

The present invention is directed, in part, to an isolated virus-like particle (formerly called lipoparticle) with a multiple membrane spanning protein of interest (*i.e.* selected by the user to be incorporated into the virus-like particle As also discussed during the interview, and evidenced by the working examples provided in the specification as filed, any enveloped virus can be used to make the particles and any multiple membrane spanning protein can be incorporated.

Indeed, the present invention is not dissimilar to that in a recent case in which the Court of Appeals for the Federal Circuit ("Federal Circuit") overturned rejections for lack of written description. See *Capon v. Eshhar*, 03-1480, 1481, *p13-p14, (Fed. Cir., August 12, 2005) (slip opinion). In *Capon,*, the claims recited chimeric DNAs (or genes) comprising DNA encoding , for example, a single chain Fv domain of a specific antibody and the transmembrane and cytoplasmic domain of an endogenous protein. *Id, at* *p5. The Board had rejected such claims for lack of written description, arguing that novel genetic material was being described in terms of the functional characteristics of the protein encoded. Id, at *9. The Board, relying upon much of the same precedent relied upon by the Office in rejecting Applicants' claims, was requiring the complete sequence of at least on chimeric gene. *Id.*, at *p11.

In response, the parties argued, *inter alia*, that the chimeric genes are produced by selecting and combining known DNA segments, using known procedures. *Id.*, at *p11. Notably, the Board did not dispute that persons in the field could determine the structure or formula from the known structure of formula of the components. *Id.* The Federal Circuit observed that none of the cases relied upon by the Board required a re-description of what was already known. *Id.*, at *p14. The court stated,

> The "written description" requirement must be applied in the context of the particular invention and the state of the knowledge. . . .When the prior art includes the [allegedly lacking] information, precedent does not set a per se rule that the information must be determined afresh.

Id., *p15. In the present case, as in *Capon*, the individual components were known.

Regardless, Applicants have sufficiently described the invention. The specification as filed discloses various types of enveloped viruses for use in the virus-like particle of the present invention. For example, at page 90, beginning at line 20, vesicular stomatitis virus, Rous-Sarcoma virus, murine leukemia virus, human immunodeficiency virus, and rabies virus, in addition to the enveloped viruses described elsewhere in the specification, are set forth. Further, the specification discloses the preparation of virus-like particles from divergent enveloped viruses: one derived from HIV—the cause of infectious disease in humans—and one derived from MLV—the cause of cancer in mice.

The specification as filed also sufficiently describes multiple membrane spanning proteins. First, a structure is provided. Applicants respectfully direct the Office's attention to page 59, beginning at line 7, where a multiple membrane spanning protein is described as a polypeptide that spans the cell membrane at least twice. Thus, contrary to the Office' assertion the protein is not without structure.

Further, the specification discloses various types of multiple membrane spanning proteins. Numerous divergent multiple membrane spanning proteins are described at page 62, beginning at line 5, of the specification. The specification discloses, for example, multiple membrane spanning proteins such as G-protein coupled receptors (*e.g*, mu-opioid receptors), as well as transporters (proteins that transport molecules such as, but not limited to, amino acids or

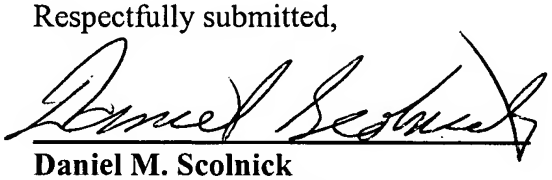
carbohydrates, across a membrane), ion channels, and the like. The specification also discloses the actual reduction to practice of virus-like particles comprising divergent multiple membrane spanning proteins, for example, the specification discloses a virus-like particle comprising the amino acid transporter (and MLV receptor) MCAT-1 (see, page 63, beginning at line 18) and virus-like particles comprising the G protein-coupled receptors CXCR4 or CCR5 (see, Example 3, page 78, beginning at line 15). Similar to *Capon*, Applicants' invention is not discovering multiple membrane spanning proteins but, rather, in the incorporation of the same in virus-like particles. *See Id.*, at *p15.

Accordingly, the skilled artisan would know that Applicants were in possession of the claimed invention at the time of filing. Applicants have demonstrated possession by describing virus-like particles comprising a variety of enveloped viruses and multiple membrane spanning proteins. Thus, for the reasons set forth above, Applicants respectfully submit that the specification as filed provides sufficient written description for the claims as presently amended, and, therefore, respectfully request reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 112, first paragraph.

Conclusion

Applicants believe the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 665-6928 to clarify any unresolved issues raised by this response.

Respectfully submitted,



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